UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Master File No. 1:13-cv-9244-RA-SDA

TAKEDA'S OPPOSITION TO PLAINTIFFS' LETTER MOTION REGARDING DOCUMENTS SUBJECT TO TAKEDA'S PRIVILEGE WAIVER

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES

Page(s)

Other Authorities

INTRODUCTION

Plaintiffs seek to invade Takeda's attorney-client privilege over broad categories of legal advice that have nothing to do with the actual subject matter as to which Takeda has informed Plaintiffs it intends to assert its reliance on the advice of counsel. Takeda agrees that the privilege may not be used as both a sword and shield, but that is not what Takeda is doing here. The law in the Second Circuit is clear—parties may waive the privilege with respect to specific subjects without forfeiting their right to maintain the privilege as to other subjects that are outside the scope of that waiver.

Takeda is asserting a regulatory compliance defense to Plaintiffs' monopolization claims, which posit that Takeda improperly maintained the listings for two of its patents for Actos in the FDA's Orange Book. Specifically, Takeda contends that it reasonably and in good faith believed, based on the advice of counsel, that its patent descriptions for the '584 and '404 patents covering Actos, submitted to FDA in 1999 and 2002, complied with the applicable pre-2003 regulations, and need not comply with the post-2003 regulations on which Plaintiffs' claims are based.[1]

Consistent with this defense, Takeda has voluntarily waived privilege over the following narrow subject matter: "[t]he applicability of the pre-2003 regulations governing the submission of patent information to FDA (21 C.F.R. § 314.53) for U.S. Patent Nos. 5,965,584 and 6,329,404 in connection with ACTOS, and Takeda's compliance with those pre-2003 regulations." ECF No. 394-1. Takeda is producing all privileged information concerning this subject matter. If a document reflects, or contains information about, the legal advice Takeda received with regard to

[1] For context, the basis for Takeda's conclusions that the pre-2003 regulations applied, and that its Orange Book listings for Actos complied with those regulations, is set forth in a May 2010 letter sent to the FDA, attached hereto as Exhibit 1.

the applicability of or compliance with the pre-2003 regulations for the '584 and '404 patents covering Actos, then that information has been or will be produced—regardless of the specific context or time period in which the document was created.

Despite Takeda's narrow subject matter waiver, Plaintiffs' Motion seeks discovery about subjects that are entirely unrelated to the applicability of or compliance with the pre-2003 Orange Book regulations and as to which Takeda has not waived. Plaintiffs' Motion therefore violates the simple and well-established rule that a privilege waiver extends only to "the same subject matter" that Takeda's defense places at issue. Fed. R. Evid. 502(a)(2). As the Court's *in camera* review will make clear, the privileged documents that Plaintiffs seek to compel Takeda to produce relate to myriad other subjects that are distinct from the applicability of, and Takeda's compliance with, the pre-2003 regulations.

Plaintiffs argue that the scope of Takeda's narrow subject matter waiver can be expanded by virtue of the good faith element of Takeda's regulatory compliance defense. Plaintiffs assert that this good faith element places at issue *all* privileged documents, regardless of subject matter, that relate to Takeda's "state of mind"—that is, whether Takeda was motivated by its efforts to comply with the law based on the regulatory advice provided by its highly-experienced outside counsel, or by anticompetitive intent. ECF No. 394 at 1, 3. Plaintiffs are wrong. As the Second Circuit recognized in its opinion issued during the second appeal in this case, the subjective good faith prong of the regulatory compliance defense tests whether "a defendant knew that an objectively reasonable statutory meaning was improper and yet still heeded it." *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 137 n.17 (2d Cir. 2021). This means that if Takeda believed that the pre-2003 regulations did not apply or that, even if applicable, Takeda believed that its conduct did not

comply with these regulations but nevertheless still engaged in the conduct, then Takeda's conduct may not constitute a good faith attempt to comply with the regulations. That is the only question that the subjective good faith prong addresses, and Takeda's waiver encompasses all otherwise-privileged documents bearing on that question.

Simply stated, the regulatory compliance defense may place at issue privileged communications concerning whether a defendant in good faith complied with the underlying regulations governing the challenged conduct (here, the Orange Book listing regulations)—not privileged communications concerning a defendant's good faith intent to comply with the antitrust laws more generally. To the extent that Plaintiffs wish to explore Takeda's purported motives for engaging in the challenged conduct, they may do so through discovery of non-privileged information.

BACKGROUND

I. Plaintiffs' Claims Challenge Takeda's Patent Submissions to the FDA

Plaintiffs allege that Takeda mischaracterized to the FDA the claims in the '584 and '404 patents. ECF No. 394. In 1999 and 2002, respectively, Takeda submitted information to FDA regarding the '584 and '404 patents for publication in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") related to Actos. *See United Food*, 11 F.4th at 127. In its submissions, Takeda described the '584 and '404 patents as both "method-of-use" and "drug product" patents. *Id.*

Plaintiffs allege that Takeda's patent listings were improper and contend that the '584 and '404 patents should have been listed only as method-of-use patents. *E.g.*, EPP 4th Am. Compl., ECF No. 255, ¶¶ 4, 5, 69, 77. According to Plaintiffs, the '584 and '404 patents claim only a method of using the active pharmaceutical ingredient in Actos (pioglitazone) in

combination with other drug products; the patents do not claim pioglitazone itself, i.e., the drug product in Actos. *Id.*

Plaintiffs' antitrust claims depend on the regulatory consequences of "drug product" versus "method-of-use" patent descriptions. Under the Hatch-Waxman Act and implementing regulations, a "drug product" patent description requires a pharmaceutical company filing an Abbreviated New Drug Application ("ANDA") for generic Actos to include a Paragraph IV certification with its ANDA certifying that the generic product does not infringe any of the patents covering the branded drug. *United Food*, 11 F.4th at 125. The Paragraph IV Certification, in turn, constitutes an automatic act of patent infringement and subjects a generic company to infringement claims brought by the brand manufacturer. *Id.* On the other hand, a "method-of-use" patent description does not require a generic to submit a Paragraph IV certification of non-infringement in all instances. *Id.* Instead, the generic may attempt to "carve out" the patented method of use from its label using a "section viii" certification or what is commonly referred to as a "skinny label." *Id.*

Most companies seeking approval for generic Actos filed Paragraph IV Certifications, and Takeda litigated and eventually settled the patent infringement claims (the "Actos ANDA Litigation") against those companies. *Id.* at 128. One company, Teva, did not file a Paragraph IV Certification and instead sought approval using a section viii "skinny label." *Id.* Plaintiffs' claims and allegations in this case parrot Teva's arguments that a Paragraph IV Certification was not required.[2]

---

[2] *See, e.g.*, Teva's Proposed Counterclaim, *Takeda Pharma. Co. Ltd. v. Teva Pharma. Inds. Ltd.*, No. 09-cv-4665 (S.D.N.Y), ECF No. 49-2, Counterclaim ¶ 3 (alleging monopolization claim based on allegations that "Takeda's misrepresentations about the '584 and '404 patents are the sole reason the FDA will require Teva to make Paragraph IV certifications that will, in turn, trigger the provisions that will necessarily delay approval of Teva's ANDA").

In August 2009, Sandoz, a generic manufacturer, filed a Citizen Petition with the FDA arguing that the agency should not approve a generic Actos product (like Teva's) that sought approval using only a skinny label and not a Paragraph IV Certification. In November 2009, Takeda submitted a letter to FDA "confirm[ing]" that the '584 and '404 Patents contain both method-of-use and drug product claims, and, thus, a Paragraph IV certification rather than a section viii skinny label is required for generic applications.[3] In January 2010, Takeda submitted a Comment to the Sandoz's Citizen Petition on the publicly available FDA docket, taking the same position it took in its November 2009 letter, and attached that letter to its public Comment.[4] Plaintiffs allege that Takeda's November 2009 and January 2010 submissions to the FDA were improper because they maintained the allegedly false Orange Book listings (from 1999 and 2002) for the '584 and '404 patents. *United Food*, 11 F.4th at 128.

In March 2010, the FDA granted Sandoz's Citizen Petition and required generic applicants like Teva to include Paragraph IV certifications as to the '584 and '404 patents in ANDAs for generic Actos. *Id.* Plaintiffs allege that, but for Takeda's allegedly improper patent listings, generics would have been able to use skinny label to "carve out" the '584 and '404 patents, rather than file Paragraph IV Certifications and litigate patent infringement cases against Takeda, and thus generics would have been able to launch their products sooner than they ultimately did. *Id.*

Importantly, none of Plaintiffs' remaining claims in this case challenges or otherwise alleges that there was anything unlawful about Takeda's prosecution or settlement of the patent

---

[3] Takeda 11/23/2009 Letter to FDA, *available at* https://www.regulations.gov/comment/FDA-2009-P-0411-0008.

[4] Takeda 1/22/2010 Letter to FDA, *available at* https://www.regulations.gov/comment/FDA-2009-P-0411-0008.

infringement claims against the generics.[5] The only alleged conduct forming the basis for Plaintiffs' claims is Takeda's decision in November 2009 and January 2010 to maintain its patent descriptions in the Orange Book for the '584 and '404 Patents for Actos.[6]

II. Takeda's Regulatory Compliance Defense

Takeda is asserting a regulatory compliance defense. The regulatory compliance defense has two elements: (1) Takeda objectively "had a reasonable basis in regulatory policy to conclude" that its actions were required by regulation, and (2) Takeda subjectively "in good faith concluded" that its actions were required by regulation. *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1138 (7th Cir. 1983); *see also In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 13 (1st Cir. 2020). As the First Circuit explained in an analogous case involving monopolization claims based on allegedly improper Orange Book patent listings:

> We therefore hold that the facts and reasonable inferences found in the complaint describe an improper submission of the [] patent for listing in the Orange Book; [and] that the defenses to antitrust liability as a result of such an improper submission include proving that the submission was the result of a reasonable, good-faith attempt to comply with the Hatch-Waxman scheme.

Lantus, 950 F.3d at 14.

Plaintiffs have long been on notice that Takeda is asserting a regulatory compliance defense. Indeed, in the prior briefing submitted to this Court in 2019 in connection with setting a deadline by which Takeda would elect whether it would waive privilege as part of its defense, Plaintiffs wrote that "Takeda asserts an affirmative defense of "regulatory compliance"" and

---

[5] All claims challenging the Actos ANDA litigation/settlement have been dismissed. *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 RA, 2015 WL 5610752, at *10-20 (S.D.N.Y. Sept. 22, 2015), *aff'd in part, vacated in part,* 848 F.3d 89 (2d Cir. 2017).

[6] The Second Circuit has previously ruled that the initial submission of patent information for the '584 and '404 patents in Orange Book, in 1999 and 2002, did not cause the alleged harm. *See In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 98-99 (2d Cir. 2017); *United Food*, 11 F.4th at 129.

noted that Takeda's Fourth Affirmative Defense (pleading that "Takeda's actions were taken in good faith") "assert[ed], in essence, a regulatory compliance defense." DPP Action, No. 15-3278, ECF No. 183 at 4. Recognizing that Takeda might seek to assert reliance on counsel in support of that defense, Plaintiffs pressed Takeda to inform them whether it intended to do so. *See, e.g.*, ECF No. 308 (Tr. of 12/10/19 Conf.) at 9:25-11:15).

III. Takeda's Election to Waive Privilege Over the Applicability of, and Compliance with, the Pre-2003 Orange Book Listing Regulations

On April 22, 2022, the deadline set in the Court's scheduling order (ECF No. 374), Takeda notified Plaintiffs that it was electing to waive privilege over the following subject matter relevant to the regulatory compliance defense: "[t]he applicability of the pre-2003 regulations governing the submission of patent information to FDA (21 C.F.R. § 314.53) for U.S. Patent Nos. 5,965,584 and 6,329,404 in connection with ACTOS, and Takeda's compliance with those pre-2003 regulations." ECF No. 394-1. Takeda did not elect to waive the privilege as to everything that might relate to its state of mind, regardless of subject matter.

Thereafter, on May 20, 2022, again in accordance with the Court's scheduling order (ECF No. 374), Takeda produced the privileged documents from its agreed-upon data sources (custodial and non-custodial) that are within the scope of the privilege waiver. The parties have since agreed to add additional data sources (for example, documents collected from Takeda's regulatory counsel, Hogan Lovells), and Takeda is continuing to produce privileged documents within the scope of the waiver from these sources.[7]

[7] Takeda has agreed to collect, review, and produce documents from Hogan Lovells, which served as Takeda's regulatory counsel advising on certain Actos issues including the applicability of and compliance with the pre-2003 Orange Book listing regulations. The parties have worked with Hogan Lovells to negotiate a search protocol and Takeda has committed to make rolling productions of the Hogan documents that are responsive and not privileged or within the scope of the privilege waiver. Takeda made its first production on September 2, 2022.

To be clear, Takeda has not selectively produced only those documents that it deems favorable to its defense. Rather, it has produced all privileged documents containing information that reflects or concerns the legal advice it received relating to the subject matter of its waiver, specifically, documents concerning the applicability of and compliance with the pre-2003 Orange Book listing regulations for the '584 and '404 patents covering Actos.[8] These documents arise in various contexts, including: (i) Takeda's 2009 and 2010 correspondence and submissions to FDA concerning Sandoz's Citizen Petition; (ii) Takeda's draft (never filed) opposition to Teva's March 2010 motion in the ANDA litigation for leave to add a counterclaim challenging Takeda's '584 and '404 Patent listings as anticompetitive; (iii) Takeda's May 2010 letter responding to Teva's challenge pursuant to 21 C.F.R. § 314.53(f) to Takeda's '584 and '404 patent listings; and (iv) Takeda's July 2010 letter to FDA explaining, in the context of voluntarily amending patent "use codes," that the '584 and '404 patents were initially listed in 1999 and 2002, respectively, and thus governed by the pre-2003 regulations.

Takeda has not, however, produced privileged documents arising in these various contexts that address subject matters beyond its narrow subject matter waiver. Takeda has not, for example, produced privileged documents that only concern its draft complaints, discovery responses, or settlement agreements in the Actos ANDA litigations. Those documents are properly withheld as privileged and logged on Takeda's categorical privilege log (categories 1, 2,

[8] After filing their Motion, Plaintiffs brought to Takeda's attention for the first time a privileged email thread, written partially in Japanese, that Takeda withheld in part as privileged (TAK-ACTOS_000524308). Takeda reviewed the English-translated document further and agreed to produce the entire privileged document in full because it was within the scope of the privilege waiver. Takeda gave Plaintiffs the opportunity to select another document from privilege log Category 3 for *in camera* review, but Plaintiffs declined and instructed Takeda to include TAK-ACTOS_000524308 for *in camera* review even though treatment of this document is no longer disputed.

and 4, respectively), as well as separately logged on Takeda's metadata log.[9] Additionally, certain documents produced pursuant to the privilege waiver still contain privilege redactions because those documents also discuss subjects as to which Takeda has not waived its privilege.

LEGAL STANDARD

Principles of fairness govern the scope of a privilege waiver. "[P]rivilege cannot at once be used as a shield and a sword." *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991). Accordingly, privilege may "be waived when [the] defendant asserts a claim that in fairness requires examination of protected communications." *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15CIV7488CMJCF, 2017 WL 2226591, at *3 (S.D.N.Y. May 19, 2017) (quoting *Bilzerian*, 926 F.2d at 1292).

In the Second Circuit, four principles have emerged that should guide this Court's analysis of the scope of the privilege waiver. First, the scope of a privilege waiver "should be formulated with caution" in favor of protecting the attorney-client privilege. *In re Cnty. of Erie*, 546 F.3d 222, 228 (2d Cir. 2008).

Second, the scope of a privilege waiver must be decided "on a case-by-case basis . . . depend[ing] primarily on the specific context in which the privilege is asserted." *In re Grand*

[9] Takeda's categorical privilege conforms to the Court's Orders (ECF No. 367, 377) and the exemplar categorical log noted by the Court (ECF No. 367 at 7). The version of Takeda's categorical privilege log that Plaintiffs attach to their Motion is incomplete—it does not include the appendices to the log identifying the participants in each privileged communication and which of those participants are U.S. attorneys or Japanese bengoshi or benrishi. Further, although not required to do so, Takeda also provided Plaintiffs with a document-by-document metadata log for documents in certain privilege log categories (selected by Plaintiffs), along with redacted copies of fully-privileged scanned paper documents that did not contain date, sender, or author metadata information. Plaintiffs' accusations that Takeda's privilege logs are "defective" (ECF No. 394 at 1) or "inadequate" (ECF No. 399), or that Takeda delayed providing Plaintiffs with the information it needed to assess Takeda's claims of privilege, are unfounded and ignore the Court's prior rulings as to the privilege log (ECF Nos. 367, 377).

Jury Proc., 219 F.3d 175, 183 (2d Cir. 2000); *see also Leviton Mfg. Co. v. Greenberg Traurig LLP*, No. 09-cv-8083, 2010 WL 4983183, at *3 (S.D.N.Y. Dec. 6, 2010) (waivers must be assessed "in the specific context in which the privilege has been asserted, rather than on the basis of generalizations.").

Third, where, as in this case, a party waives privilege over a subject matter that is relevant to its defense, the waiver extends only to "other communications relating to the same subject matter." *See, e.g.*, *Regeneron Pharms., Inc. v. Merus B.V.*, No. 14 CIV. 1650 (KBF), 2014 WL 11344040, at *4 (S.D.N.Y. Dec. 5, 2014); Fed. R. Evid. 502(a)(2).

Fourth, "the mere fact that a privileged communication may be relevant to a claim or defense is insufficient to forfeit protection." *Namenda,* 2017 WL 2226591, at *3 (citing *In re Cnty. of Erie*, 546 at 229). "Rather, a [party] may waive protection where he asserts a factual claim the truth of which can only be assessed by examination of a privileged communication." *Id.*; *see also Scott v. Chipotle Mexican Grill, Inc.*, 67 F. Supp. 3d 607, 611 (S.D.N.Y. 2014) (privilege waived if claim or defense "can only be scrutinized by examining the disputed [privileged] communications").

ARGUMENT

I. Takeda Is Not Using Privilege As Both a Sword and a Shield

Plaintiffs' Motion should be denied for the simple reason that Takeda is already providing the relief requested by Plaintiffs: Takeda is already producing "all evidence," including privileged documents, "relevant to its good faith regulatory compliance defense." ECF No. 394 at 1. In asserting its regulatory compliance defense, Takeda contends that its decision to maintain its '584 and '404 patent submissions was a reasonable and good faith attempt to comply with the law because Takeda understood, based on the advice of highly-experienced and

qualified outside counsel, that the pre-2003 Orange Book listing regulations (21 C.F.R. § 314.53) governed and that Takeda's patent submissions complied with those regulations.

Rather than "pick[ing] and choos[ing] between what opinions will be relied upon and which will be discarded," *cf. United States v. Locascio*, 357 F. Supp. 2d 536, 552 (E.D.N.Y. 2004), Takeda is producing all privileged information concerning the subject matter that its defense has placed at issue. Takeda is producing this information in all contexts and at all points in time when the subject matter arose—from Sandoz's 2009 Citizen Petition, to Teva's 2010 challenges to Takeda's patent listings, to Takeda's July 2010 correspondence with the FDA relating to voluntarily amending the patents' use codes. *Cf. id.* at 550-53 (holding that party's reliance of advice of counsel as to compliance with FTC's unfair or deceptive advertising regulations for mail order advertisements also waived privilege as to advice received regarding the same FTC regulations applied to internet advertisements).

As apparent from Takeda's privilege log and as the Court will see in its *in camera* review, the documents that Takeda continues to withhold as privileged do not relate to "the same subject matter"—the applicability of and compliance with the pre-2003 regulations—that Takeda's reliance on the advice of counsel for its regulatory compliance defense places at issue. Instead, they concern different subject matters as described in Takeda's categorical privilege log descriptions (e.g., privilege log categories 1 through 5, which relate to prosecution and settlement of the Actos ANDA litigation). Takeda has not waived its privilege over these other subjects.[10]

[10] Takeda has notified Plaintiffs that when it produced two multi-page scanned paper documents with privilege redactions, it inadvertently did not redact privileged information in these documents concerning a settlement conference in the Actos ANDA litigation that did not relate to the applicability of and compliance with the pre-2003 regulations. *See* ECF No. 394-6 at 7 (TAK-ACTOS_000527117) & 10 (TAK-ACTOS_000527130). Takeda intends to maintain

II. The Good Faith Element of Takeda's Regulatory Compliance Defense Does Not Broaden the Privilege Waiver to Other Privileged Subject Matters

Plaintiffs attempt to broaden Takeda's waiver by arguing that the good faith element of the regulatory compliance defense places at issue all privileged documents, regardless of subject matter, that relate to Takeda's "state of mind"— that is, whether Takeda was motivated by its good faith regulatory interpretation or by anticompetitive intent to delay generic drug entry. ECF No. 394 at 1, 3. Plaintiffs' argument fails for at least two reasons.

First, Plaintiffs' argument has no support in the law. As the Second Circuit stated in its opinion issued during the second appeal in this case, the subjective good faith prong of the regulatory compliance defense tests whether "a defendant knew that an objectively reasonable statutory meaning was improper and yet still heeded it." *United Food*, 11 F.4th at 137 n.17 (emphasis added); *see also Lantus*, 950 F.3d at 13 (stating that subjective prong of regulatory compliance defense places at issue "what if any legal opinions [defendant] sought and obtained before submitting the patent"); *United States v. Exxon Corp.*, 94 F.R.D. 246, 249 (D.D.C. 1981) ("[T]he only way to assess the validity of Exxon's affirmative defenses, voluntarily injected into this dispute, is to investigate attorney-client communications where Exxon's interpretation of various DOE policies and directives was established and where Exxon expressed its intentions regarding compliance with those policies and directives. There is no other reasonable way for plaintiff to explore Exxon's corporate state of mind, a consideration now central to this suit."). Applied here, this means that if Takeda actually believed that the pre-2003 regulations did not apply, or that, even if applicable, Takeda believed that its conduct did not comply with these

---

privilege over this settlement conference in the Actos ANDA litigation and these two documents will be logged in Category 5 of Takeda's categorical privilege log. Pursuant to Section 11 of the Stipulated Protective Order (ECF No. 190), the inadvertent production does not constitute a waiver of the attorney-client privilege or work product protection.

regulations, but it engaged in the conduct anyway, then Takeda's conduct may not be a good faith attempt to comply with the regulations. The regulatory compliance defense may place at issue privileged communications concerning whether a defendant in good faith complied with the underlying regulations governing the challenged conduct (here, the Orange Book listing regulations)—not privileged communications concerning a defendant's good faith intent to comply with the antitrust laws more generally.

The D.C. Circuit's opinion in *Southern Pacific Communications Co. v. American Telephone & Telegraph Co.*, 740 F.2d 980 (D.C. Cir. 1984), while not controlling here, is in accord. Plaintiffs cherry pick language from the court's opinion that they believe justifies broad discovery into privileged state-of-mind documents: the "regulatory justification defense is only applicable if [the party's] asserted 'public interest' basis for its interconnection decision is reasonable and if AT&T actually made its decision at the time in good faith on that basis rather than solely on the basis of competitive considerations." *Id.* at 1009. But *Southern Pacific* did not involve and does not address a privilege waiver, or its scope, at all. It therefore cannot support Plaintiffs' incredible position that waiving privilege as to the advice the company received about how to comply with patent listing regulations places at issue any other privileged communications that may bear on the company's state of mind or intent to comply with the antitrust laws. Instead, the court in *Southern Pacific* held that the district court properly considered the subjective element of the regulatory compliance defense when the court examined documents that purported to show that defendant "knew that its conduct was inconsistent with the FCC's order." *Id.* at 1011. Takeda has waived privilege over that subject (whether it complied with the pre-2003 listing regulations). If the Plaintiffs wish to probe further into whether Takeda acted with anticompetitive intent, they may do so with non-privileged

information—exactly as the parties did in *Southern Pacific*. *See id.* at 1110-11; *see also Scott*, 67 F. Supp. 3d at 611 (privilege waived if defense "can **only** be scrutinized by examining the disputed [privileged] communications" (emphasis added)); *Namenda*, 2017 WL 2226591, at *3 (same).

Second, Plaintiffs' fishing expedition for any and all privileged state-of-mind information does not concern the "same subject matter," Fed. R. Evid. 502(a)(2), placed at issue by Takeda's regulatory compliance defense. Plaintiffs seek, for example, privileged documents concerning Takeda's prosecution and settlement of the Actos ANDA litigation. ECF No. at 3. But Plaintiffs' remaining claims in this case do not challenge, and thus Takeda's regulatory compliance defense does not relate to, whether Takeda prosecuted and settled the Actos ANDA litigation in good faith. These patent litigation and settlement documents thus remain privileged—as Plaintiffs' own cases recognize. For example, in *United States v. Locascio*, 357 F. Supp. 2d 536 (E.D.N.Y. 2004), the court held that "all knowledge gained by the infringer **relating to the advice subject matter** must be revealed so that the factfinder can make its own determination as to whether the reliance was reasonable." *Id.* at 552 (emphasis added; citation omitted).[11] And Takeda is producing all information relating to the subject matter of its regulatory compliance defense in this case. Indeed, if there is a privileged document created in the context of the Actos ANDA litigation or settlement that discusses the applicability of and compliance with the pre-2003 regulations, Takeda has produced it. *See, e.g.*, ECF No. 394-6 at 1

[11] *See also id.* at 551-52 ("The court held that by raising the defense of reliance on counsel, defendants also raised the issue of 'reasonableness of [their] state of mind in relying on legal advice from counsel for the seller that it was safe to proceed with the transaction.' The court held that, 'the legal advice they received from any other lawyers **on that subject** relates to the reasonableness of defendants' reliance and is not subject to the attorney/client privilege,' essentially because these communications were relevant to their state of mind in proceeding to acquire and operate the company." (emphasis added; citation omitted)).

(TAK-ACTOS_000513468). Plaintiffs' Motion attempting to expand the privilege waiver into other privileged subject matters that are not placed at issue by Takeda's regulatory compliance defense should be denied.

CONCLUSION

For the reasons set forth above, Plaintiffs' Motion should be denied in full.[12]

Respectfully submitted,

Dated: September 6, 2022

/s/ Steven A. Reed

Steven A. Reed (admitted *pro hac vice*)
R. Brendan Fee (admitted *pro hac vice*)
Melina R. DiMattio (admitted *pro hac vice*)
D. Patrick Huyett (admitted *pro hac vice*)
Mark J. Fanelli (admitted *pro hac vice*)

MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103
Telephone: (215) 963-5000
steven.reed@morganlewis.com
brendan.fee@morganlewis.com
melina.dimattio@morganlewis.com
patrick.huyett@morganlewis.com
mark.fanelli@morganlewis.com

Attorneys for Defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc.

[12] Plaintiffs' letter motion broadly challenges Takeda's privilege assertions as to multiple categories, implicating over 3,300 documents that were properly withheld as privileged. Takeda cannot fully address each category given the page limitations of this brief. To the extent the Court has further questions about what is properly within the scope of the waiver after it has reviewed example documents *in camera*, Takeda respectfully requests a further opportunity for briefing and a hearing as to the specific categories and privileged documents at issue.